United States Department of Agriculture
Food Safety And Inspection Service
Technical Service Center
Suite 300, Landmark Center
1299 Farnam Street
Omaha. NE 68102

AUDIT REPORT FOR THE REPUBLIC OF IRELAND

NOVEMBER 12 THROUGH 27, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of the meat inspection system of the Republic of Ireland (hereinafter called Ireland) from November 12, 2001 through November 27, 2001. The four establishments certified to export meat to the United States were audited. Three of these were slaughter establishments, and one was conducting processing operations.

The last audit of the Irish meat inspection system was conducted in April-May 2000. Six establishments were audited: three were acceptable; one was evaluated as acceptable/re-review, and two were found to be unacceptable. The following major concerns were identified at that time:

1. Hand-washing facilities were inadequate in two establishments, and workers were not washing their hands as required in two others.

2. Lighting was found to be inadequate at inspection stations in all the slaughter establishments.

3. Turnaround times in the residue testing laboratories did not meet FSIS expectations.

4. The intra-laboratory check sample programs in the residue testing laboratories did not meet FSIS requirements.

The importation of meat products from Ireland was not allowed at the time of this audit due to the presence of Bovine Spongiform Encephalopathy and Foot-and-Mouth Disease. Until January 2001, the only restriction on pork products had been that the product must be indigenous and processed in a dedicated establishment that receives no animals from countries where Swine Vesicular Disease exists (these conditions were fulfilled in Ireland). In January 2001, an outbreak of (FMD) occurred in Great Britain, with the result that pork from Ireland was also not allowed entry into the U.S.

From January 1 through September 30, 2001, three establishments (332, 355, and 356) exported 1,067,984 pounds of pork and pork products to the United States. Only 241 pounds (less than 0.03%) was rejected at ports of entry (POE) for missing shipping marks.

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Irish national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the on-site visits. The third was conducted by on-site visits to establishments. The fourth included visits to (1) three government laboratories performing analytical testing of field samples for the national residue testing program, (2) a private laboratory culturing field samples for the presence of microbiological contamination with *Salmonella* species and generic *Escherichia coli*, (3) a pig farm, and (4) a cattle feed lot.

Ireland's program effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the generic *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination /adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials (this was the case with one establishment—see below).

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in three of the four establishments audited; two of these (Ests. 332 and 738) were acceptable and one (Est. 355) was recommended for re-review. One establishment (356) was found to be unacceptable. Details of the audit findings, including compliance with HACCP programs, SSOPs, and testing programs for *Salmonella* and generic *E. coli*, are discussed later in this report.

As stated above, four major concerns had been identified during the 2000 FSIS audit:

1. *Hand-washing facilities had been inadequate in two establishments, and workers were not washing their hands as required in two others.* During this new audit, hand-washing facilities were inadequate in one establishment (this was a repeat finding).

2. *Lighting had been found to be inadequate at inspection stations in all the slaughter establishments.* This had been addressed and resolved in all slaughter establishments.

3. *Turnaround times in the residue testing laboratories did not meet FSIS expectations.* This had not been adequately addressed or corrected. Some improvement was noted in one laboratory, but the same deficiency was noted again, to varying degrees, in all three residue laboratories.

4. *The intra-laboratory check sample programs in the residue testing laboratories did not meet FSIS requirements.* This was a repeat finding.

In addition to the above, the following deficiencies were cause for major concern during this new audit:

1. None of the slaughter establishment management officials had developed a statistical process control, as required, to evaluate the results of the generic *E. coli* testing.

2. Insanitary storage of product was found in two of the four establishments.

Entrance Meeting

On the morning of November 12, an entrance meeting was held in the Dublin offices of the Department of Agriculture, Food, and Rural Development (DAFRD), and was attended by Mr. Paddy Rogan, Deputy Chief Veterinary Officer; Mr. Frank Kenny, Senior Superintending Veterinary Inspector (Agriculture House); Mr. Kilian Unger, Superintending Veterinary Inspector; Mr. Paul Rafter and Dr. Montse Gutierrez, Central Meat Control Laboratory; Ms. Marie Hoban, District Administration Division; Ms. Dierdre Dordan, Veterinary Medicines Section; Mr. Philip Kirnan, Animal Health & Welfare Division, Ms. Eibhlin O'Leary, Contracts Manager, Food Safety Authority of Ireland; and Ms. Jarlath Coleman, Food Safety Liaison Unit. FSIS was represented by Mr. Michael Hanley, Agricultural Attaché, American Embassy Dublin; Mr. Steve McDermott, International Policy Staff Officer; Dr. Judd Giezentanner, International Audit Staff Officer; and Dr. Gary D. Bolstad, International Audit Staff Officer and lead auditor, hereinafter called the Auditor. The topics of discussion included the following:

1. The Irish meat inspection officials were informed of the timeline for the country audit report: a draft of the report would be provided to them within 60 days of the exit meeting in Dublin; they would have another 60 days to review the contents and provide comments to FSIS, and when a consensus on the material was reached between FSIS and DAFRD, the final report would be posted in the FSIS Home Page.

2. The Auditor explained that the purpose of the audit was to establish whether the inspection system controls continued to ensure that products that were eligible to enter the U.S. export chain were produced either in compliance with the applicable European Commission (EC) Directives agreed to in the Veterinary Agreement between the EC and FSIS or, regarding FSIS requirements in those areas where these EC Directives did not apply (for example, SSOPS and HACCP/PR programs), under conditions equivalent to those required in U.S. domestic establishments. The three EC Directives that had been agreed upon as equivalent to FSIS requirements were:

- Council Directive 64/433: Health problems affecting intra-community and trade in fresh meat,
- Council Directive 96/22: Prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and
- Council Directive 96/23: Measures to monitor certain substances and residues thereof in live animals and animal products.

3. The Auditor ensured that the Irish officials were informed regarding the Website location of the FSIS Enforcement Quarterly Report and inquired whether Ireland also made similar information available to the public; the Irish officials replied that the results of the Government of Ireland's (GOI) enforcement activities were not generally made available to the public at the time, but that there were plans to do so in the foreseeable future; in the meantime, the information was available to the public through Ireland's Freedom of Information Act.

4. The Auditor provided copies of the data-collection instruments he would be using in the audits of the individual establishments (Attachments A, B, C, and D).

5. Information was provided to update the FSIS country profile for Ireland.

Headquarters Audit

The DAFRD officials provided a summary of the changes in the organizational structure and upper levels of inspection staffing since the last U.S. audit of Ireland's inspection system.

To gain an accurate overview of the effectiveness of inspection controls, FSIS had requested that the audits of the individual establishments be led by the inspection officials who normally conducted the periodic reviews for compliance with U.S. specifications. The Auditor observed and evaluated the process.

The auditor conducted a review of inspection system documents at the Dublin headquarters of the inspection service. This records review focused primarily on food safety hazards and included the following:

- New laws/regulations/directives/ guidelines,
- Copies of official communications with field personnel, both in-plant and supervisory, in which U.S. requirements (including monitoring and documenting the establishments' compliance with the requirements of SSOPs and HACCP/Pathogen Reduction programs) were conveyed,
- Supervisory visits to U.S. certified establishments,
- Consumer complaints and product recall actions,
- The current animal disease status,
- Enforcement records, including examples of non-compliance records and the related forms used in case of further non-compliance, records of criminal prosecution, and seizure and control of noncompliant product,

- Labeling records,
- Internal review reports, and
- Export product inspection and control.

No concerns arose as a result the examination of these documents.

Government Oversight

The official government inspection duties of Ireland's meat inspection system were being carried out by DAFRD Veterinary Inspectors and Agricultural Officers, neither of whom receive any remuneration from either industry or establishment personnel.

The DAFRD is Ireland's central government authority responsible for direct oversight of Ireland's exporting meat inspection system and operates under the auspices of the Food Safety Authority of Ireland (FSAI). The FSAI was established on January 1, 1998, as having all responsibilities for the enforcement of food safety in Ireland. The FSAI had, by contract with DAFRD, delegated responsibility to enforce food safety regulations relating to establishments certified to export meat to the United States and to government and private laboratories conducting microbiology, chemistry, and residue analyses of samples of meat destined for the U.S. market. The DAFRD also has responsibility for animal feed lots and farms associated with the production of meat for export.

At the time of this audit, there were 28 District Veterinary Offices, mainly county-based (the two largest counties, Tipperary and Cork, each had two Districts. Each District Veterinary Office supervised a number of Veterinary Inspectors. The DAFRD had approximately 1,150 official government Veterinary Inspectors and Agricultural Officers assigned to Ireland's exporting meat and poultry establishments. Each slaughter facility had a Veterinary Inspector in charge that had direct authority over the government inspection activities in the establishment and responsibility for the duties of other government veterinarians and Agricultural Officers assigned to the establishment. Each DAFRD-approved establishment was fully staffed to handle the government inspection duties, which included ante-mortem, post-mortem, and sanitation inspections, as well as oversight of the establishment's HACCP/PR and SSOP responsibilities.

The DAFRD Veterinary Inspector in charge had the authority to cease the establishment's production operations any time the wholesomeness and safety of the product is jeopardized. He/she reported directly to a DAFRD Regional Superintending Veterinary Inspector (RSVI), who in turn reported directly to a Senior Superintending Veterinary Inspector (SSVI) at DAFRD headquarters. Two SSVIs located at DAFRD headquarters in Dublin and six RSVIs located in regional offices throughout Ireland carried the responsibility for the exporting meat and poultry establishments.

During this audit, DAFRD demonstrated an adequate amount of supervisory oversight, and a sufficient number of inspection personnel had been assigned to the four meat establishments certified by DAFRD as eligible to export meat products to the United States. Furthermore,

DAFRD demonstrated sufficient government oversight at the three government residue-testing laboratories, the private microbiology laboratory, the cattle feed lot, and the pig farm visited during this audit.

However, even though the government of Ireland demonstrated satisfactory oversight and supervision of the production of meat for export to the United States, the number of deficiencies found in the exporting establishments and government laboratories, of which some were noted during the last FSIS audit, indicated ineffective corrective actions and/or preventive measures taken by DAFRD in some areas. With the exception of the findings at Establishment 356, the deficiencies observed appeared not to have direct impact on food safety.

Establishment Audits

Four establishments were certified to export meat products to the United States at the time this audit was conducted; all were visited for on-site audits. In three of the four establishments, both DAFRD inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products. The other (Est. 356) was found by the DAFRD officials leading the audit to fail to meet basic U.S. requirements and was removed by them from the list of establishments eligible to export meat products to the United States, effective as of the start of operations on the day of the audit.

Laboratory Audits

During the four laboratory visits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information about the following risk areas was also collected:

- Government oversight of accredited, approved, and private laboratories.
- Intra-laboratory quality assurance procedures, including sample handling.
- Methodology.

The Central Meat Control Laboratory in Dublin was audited on November 20, 2001. Effective controls were in place for sample handling, data reporting, tissue matrices for analysis, minimum detection levels, and recovery frequency. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency). This laboratory was owned and operated by the Department of Agriculture, Food, and Rural Development (DAFRD), but it had not been accredited. Accreditation was expected to be achieved within the next six months. The following deficiencies were identified:

- Turnaround times (the amount of time from reception in the laboratory until the analyses are complete) for heavy metals were as long as 8 to 10 months, and for stilbenes two months. FSIS expects turnaround times of one month. The laboratory director explained that the section of the laboratory housing the equipment for heavy

metals had been under extensive construction since early in the year, and that timely analysis would soon resume. Turnaround times had been found deficient for all classes of compounds during the previous FSIS audit of this laboratory (4/28/2000); the turnaround times were now within expected limits for all other classes. For most classes of compounds, the number of analyses to date was within expectations with regard to the number of analyses required in the national residue-testing plan. For beta-agonists, however, 2,040 samples were to be taken during the calendar year but, as of the end of September, only 649 samples had been completed. It was noted that the outbreak of Foot-and-Mouth Disease early in the year had caused hardships with meeting the projected quotas.

- FSIS requires that each analyst must participate in a check sample program, at least once per calendar month, for each class of substances for which he/she performs the field analyses for the national residue testing program. No intra-laboratory check samples were being performed for any of the compounds requiring radioimmune assay (stilbenes, beta-agonists, chloramphenicol, and sedatives) or for antibiotics. The laboratory director explained that a source of reference material containing known amounts of these com-pounds was being sought, and that a potential source had been located in Trieste, Italy. Also, a permanent quality assurance (QA) manager and four additional technicians were expected to be added to the staff within six weeks, so that the requirements were expected to be met within several months. International check samples for heavy metals were analyzed every four months. Intra-laboratory check samples were provided to analysts for the screening tests, prepared from past positive samples, but none for quantitative analysis.

- No confirmatory testing for antibiotics and tetracyclines had been performed since January 2001 on field samples that had tested positive on screening tests. Carcasses that had been sampled as a result of suspicion of residues (with tentative injection sites) and that had tested positive on the antibiotic screening test were condemned. Positive samples from carcasses sampled randomly were being held until confirmatory methods would be in place; this was expected to occur within the next 6 to 12 months. There had been very few (six) positive random samples since the start of the calendar year.

- This laboratory had been functioning without a Quality Assurance (QA) manager for more than two and a half years. A new acting QA manager had been in place for the past 3-4 months, but no written corrective action program had as yet been developed. This person was aware of the requirement and expected to have one implemented within the next six months.

- No percent recoveries were available for antibiotics or tetracyclines, because the confirmatory tests were under development.

Note: In all sections of the laboratory, deficiencies noted during the previous FSIS audit regarding the standards books had been addressed and corrected.

The Pesticide Control Service Laboratory in Dublin was also audited on November 20, 2001.

Effective controls were in place for sample handling and frequency, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, and percent recoveries. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency). The following deviations from FSIS requirements were identified:

- Turnaround times (the amount of time from reception in the laboratory until the analyses are complete) were as long as two months. This was a repeat finding. FSIS expects turn-around times of one month. The laboratory director state that new additions to the staff were expected to be in place by mid-2002, and that the one-month target for turnaround times was expected to be reached shortly thereafter.

- No intra-laboratory check sample program was implemented. Spiked (positive control) samples were being run together with each sample set. The Auditor explained the requirement, and that they were expected to be provided to each analyst at least once per month, for proficiency assurance; Dr. O'Sullivan proposed using past samples that had tested positive as intra-laboratory check samples.

- The written corrective action programs were only approximately 80% complete; they were expected to be fully implemented by May 2002.

The State Laboratory in Abbotstown, Dublin was visited on November 21. Analyses performed here for the national residue-testing program were for nitroimidazoles and non-steroidal anti-inflammatory drugs. Effective controls were in place for sample handling and frequency, data reporting, tissue matrices, equipment operation and printouts, minimum detection levels, recovery frequency, and percent recoveries. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency). The following deviations from FSIS requirements were identified:

- Samples to be analyzed for both classes of compounds were held in a freezer and analyzed once toward the end of the year, so turnaround times ranged up to nearly one year. FSIS expects turnaround times of one month.

- A gas-chromatography mass-spectrometer was used for screening for non-steroidal anti-inflammatory drugs; no confirmatory or quantitative method was currently in place; one was expected to be in operation within the next few months.

- No intra-laboratory check sample program was in place for either class of compounds.

- The standards book for non-steroidal anti-inflammatory drugs consisted of individual, not serially numbered sheets kept in a loose-leaf notebook. Expiration dates were noted, but were not heeded: A standard solution of Flunixin had been prepared in September 2000 from a vial that had an expiration date of March 1998 and another standard solution had been prepared from the same expired vial in November 2001. (There was a comment in the entry for the September 2000 preparation that read: "still detectable." There were no comments in the entry for the November 2001 preparation.)

- The standards book for nitroimidazoles lacked information about the expiration dates of the analytes.

The Central Veterinary Services Laboratory in Abbotstown, Dublin was visited on November 20. This laboratory was responsible for approving the procedures used in the laboratories that process the field Salmonella samples, and was in the process of developing the Irish national Salmonella testing program for the poultry program for the next year. A similar program was proposed for swine, and was expected to be implemented some time in 2002. The Director of this laboratory reported directly to the Chief Veterinary Officer, Dr. Colm Gaynor. No concerns arose as a result of the visit.

Ireland's microbiological testing for *Salmonella* was being performed in private laboratories. One of these, the Independent Micro Laboratory, Ltd. In Dungarvan, County Waterford, was audited on November 14. The Auditor determined that the system met the criteria established for the use of private laboratories under FSIS's HACCP/Pathogen Reduction rule. These criteria are:

1. The laboratory has been accredited/approved by the government, accredited by third party accrediting organization with oversight by the government, or a government contract laboratory.

2. The laboratory has properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.

3. Results of analyses are being reported to the government or simultaneously to the government and establishment.

Effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices, an intra-laboratory check sample program, and a written corrective action program. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency).

Samples for microbiology may be composited if so requested by individual clients. The laboratory personnel available on the day of the audit did not know whether the establishments listed for U.S. export fell into this category.

Establishment Operations by Establishment Number

The following operations were being conducted in the four establishments audited:

Specialty cooked sausage production (738)
Pork slaughter, boning, cutting, and mincing – one establishment (356)
Pork slaughter, boning, cutting, and curing – two establishments (322, 355)

SANITATION CONTROLS

Based on the on-site audits of establishments, Ireland's inspection system had controls in place for water potability, chlorination procedures, separation of establishments, pest control

programs and monitoring, temperature, lighting, work space, ventilation, dry storage areas, ante-mortem and welfare facilities, outside premises, and personnel dress and habits, equipment sanitizing, product transportation, operational sanitation, and waste disposal.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements in Ests. 332, 355, and 738. In Est. 356, however, documentation by the establishment of pre-operational findings did not reflect the conditions observed during the audit. Both the main boning room and the slaughter floor had past pre-operational sanitation inspection by establishment personnel; however, numerous obvious deficiencies had been overlooked. Details are elaborated below.

Pre-Operational Sanitation

- Establishment 356 was visited before the start of operations. The establishment had finished pre-operational sanitation inspection and the Auditor observed as the DAFRD officials performed their check. In the main boning room, product residues were found on the majority of the edible product containers ready for use; a number of these also had grease smears. On the slaughter floor, clumps of product residues were found on ceilings over-product equipment and in viscera trays. The Superintending Veterinary Officer who was leading the audit ordered both areas to be re-cleaned. When the management informed him that this had been done, he determined that the cleaning had again been inadequate.

Cross-Contamination

- No hand-soap dispensers were available at the post-mortem inspection stations in Est. 356. This was a partial repeat finding: during the 2000 FSIS audit, this deficiency had been found in two of the five slaughter establishments audited. The QA manager said this would be resolved before slaughter would begin.

- The water in sanitizers was found to be below the required temperature in two of the four establishments (Ests. 355 and 356). This was a repeat finding: the same problem had been identified in three of the six establishments during the 2000 FSIS audit. In both cases, the water temperature was brought up to standard promptly.

- Submerged water hoses without back-siphonage-prevention devices were found in Est. 355. The establishment management corrected the problem promptly.

- Floor cleaners were observed to contaminate edible-product contact surfaces in Ests. 355 and 738. Establishment management officials took appropriate actions immediately.

- Clean product moulds were stored on inadequately covered pallets in Est. 738: some of the moulds were in contact with the unclean surfaces of the pallets. The DAFRD officials ordered immediate implementation of a procedure to cover the pallets adequately.

Personal hygiene

- Both establishment and DAFRD personnel failed to wash their hands upon entering a production area in one establishment (Est. 355). This was a partial repeat finding: during the 2000 FSIS audit, this deficiency had been found in two of the six establishments audited.

- Personal hygiene deficiencies were observed in Ests. 355 and 738. Corrective actions were immediate.

Maintenance

- Neglected maintenance of over-product structures was found in two establishments (Ests. 355 and 356). This was a partial repeat finding: during the 2000 FSIS audit, this deficiency had been found in four of the six establishments audited.

ANIMAL DISEASE CONTROLS

Ireland's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, restricted product control, and procedures for sanitary handling of returned and rework product.

Beef from the Republic of Ireland was under restriction due to the presence in the country of Bovine Spongiform Encephalopathy. There had also been one case of Foot and Mouth Disease, but the full restriction on meat from susceptible species was lifted in early November 2001. Other animal diseases in the country included bovine tuberculosis and brucellosis.

In addition to the national residue testing program, Ireland had developed a "Plant's-Own Self-Monitoring Program," under which each export establishment tested 0.5% (beef) / 1% (swine) of the volume slaughtered in that establishment during calendar year 2000. Violations resulted in 25% of the subsequent stock from that supplier being sampled. If there were any further positives, 100% of that supplier's stock were sampled. In addition, any DAFRD veterinarian has the full authority to sample any animal he may deem necessary.

To address the demand for the creation of a central data base that would contain comprehensive details of the origin, identity, and location of cattle, Council Regulation 820/97 established a common European Union (EU) framework of rules for bovine animal identification and tracing and labeling of beef. The EU rules identified four "pillars of identification:" ear tags, identity cards, on-farm herd registers, and computerized data bases containing full information on animal identity and location. At the same time, at the Irish

national level, a "National Beef Assurance Scheme" (NBAS) was established, that ensured a comprehensive traceability system for Irish cattle. This had been enhanced through the implementation of a Cattle Movement Monitoring System (CMMS) that has been in effect since 1998. Under this system, an "animal passport" accompanied each animal. This passport contained:

- the name and address of the breeder,
- the animal's date of birth,
- the sex of the animal,
- the dam's ear tag number,
- a full record of tuberculosis and brucellosis testing,
- full records of all movements (e.g., livestock markets), and
- the individual animal's ear tag number. Identical tags are in each ear; the tag is alpha-numeric. Two letters represent the country; the first two digits represent the county, the next five the herd number, and the others are the individual animal's unique identification number. Each ear tag also has a bar code for rapid scanning, e.g., at slaughter.

A Clean Livestock Policy had also been in effect in Ireland since 1998: animals are divided into 5 categories of cleanliness; too-dirty animals are rejected for slaughter. This program had been added to ante-mortem inspection legislation.

♦ One deficiency was identified regarding disease control. Condemned materials (carcasses of dead-on-arrival animals, carcasses of animals condemned upon ante-mortem inspection, and carcasses condemned at post-mortem inspection) were not being denatured before leaving the premises. DAFRD officials agreed to require the establishment to initiate a program of denaturing carcasses condemned on the slaughter floor and those of swine condemned upon ante-mortem inspection.

RESIDUE CONTROLS

Ireland's National Residue Testing Plan for 2000 was being followed, and was on schedule. The Irish inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

FSIS had placed special emphasis on the verification of residue controls for the international audits conducted in 2001. As part of this verification, the Auditor interviewed DAFRD officials regarding Ireland's residue controls and paid visits to a pig farm and a cattle feedlot.

Residue Controls Meeting

A meeting on residue controls was held in the State Laboratory in Abbotstown, Castleknock, Dublin, on November 21. The DAFRD officials attending were Mr. John P. Moloney, Higher Executive Officer, Veterinary Medicine Section; Dr. Patrick Brangan, Superintending Veterinary Inspector; Dr. Liam Regan, Senior Chemist, State Laboratory; Dr. Paula Shearan,

Chemist; and Dr. Montse Gutierrez, Central Meat Control Laboratory. The following information was gathered:

The responsibility for ensuring compliance with expiration dates on medications dispensed by practicing veterinarians to the owners of farms and feedlots lies with the veterinarian who prescribed the medications. The veterinarian must have examined the animals within 60 days to prescribe medications for the farmer to administer, according to the 1996 Animal Remedies Regulation.

Additives with potential residue significance were not allowed in commercial feed in Ireland. Therapeutic feeds were produced, but they must be prescribed by a veterinarian for a documented disease condition, according to the EC's Animal Remedies and Medicated Feedingstuffs Regulation of 1994. Animal drugs used as additives in animal feed were required to fulfill the same requirements as any other veterinary drug.

Commercial feed mills were regulated by the Cereals Division of the Dept. of Agriculture. There were approximately 100 of these in Ireland; of these, about 25-30 of these were licensed to produce feeds with therapeutic additives. The latter were required to keep the medicated products stored separately and to keep separate records for receiving and outgoing products. They were required to document a check that the incoming medications were authorized by the Irish Board of Veterinary Medicine for this purpose. The Veterinary Medicine Section of the Department of Agriculture was responsible for verifying the accuracy of these documents.

A new program was planned to be started in 2002 that would sample both non-medicated feed, to ensure that it contains no medicines, and medicated feed, to determine that the prescribed medication is actually what it contains and that it is present at the prescribed level.

If a drug residue violation occurs, routine sampling of animals from that producer is increased, as outlined in EC Directive 96/23. Also, slaughter establishments are required to carry out their own increased testing. The Minister gives these establishments direction regarding how many animals to sample. Violations must be reported to the veterinary inspectors in the plant, and Agriculture House is notified separately; from here all slaughter establishments in the country are notified. For the next 3 months, the sampling of that producer's stock is increased. The meat plants then charge the producer for the cost of this testing. If there is a second violation, 100% of the animals from that producer must be tested, and all the costs for the increased sampling must born by the producer. The plant to which he brings his stock will know of the increased sampling requirement through the CMMS (Cattle Movement Monitoring System). Enforcement actions are outlined in Regulation 25 of the Control of Animal Remedies and Their Regulation of 1998.

Farmers convicted of illegal use and/or distribution of animal drugs are subject to fines, the largest of which to date has been £39,000, or over $47,000, up to an imprisonment of up to 2 years. Other food products (e.g., milk) from the farm are also examined. Furthermore, if an individual is convicted of a violation on indictment under Section 24 of the Animal Remedies Act of 1993, the court may disqualify the person from farming or from having any dealings

with animal remedies. Additionally, anything that has been used in the commission of an offense (an animal, vehicle, etc.), may and will be confiscated.

There had been a recent conviction involving clenbuterol detected following sampling of a carcass with an injection site at slaughter, by analyzing the retina. The defendant was fined some £14,000 ($17,000). There were also two other recent cases involving injection sites that yielded anabolic residues in cattle, and 3-4 other cases in which antibiotics were being held on the farm illegally or being sold illegally. There was also a successful prosecution of a farmer who had not maintained the required records regarding antibiotic use; he was fined £350 ($425)

The results of the investigations are made available to the public through national and especially local ("name and shame") press notices. Records of the proceedings are maintained by the inspection service.

No concerns arose from the discussions at this meeting.

Pig Farm

A visit was paid to a private pig farm in Woodville, Ballymackey, Nenagh, County Tipperary, on November 16. DAFRD was represented by Mr. Kilian Unger and Mr. Michael Hayes, Superintending Veterinary Officers; and Mr. Owen O'Neill, Veterinary Inspector. The "birth-to-bacon" operation consisted of 620 sows producing an average of 24 piglets per sow per year, providing an annual production of some 15,000 market pigs. Approximately 300 pigs were sent to market each Monday. Artificial insemination was used. This was a "closed-unit" operation: no pigs from outside sources entered the premises.

The piglets suckled for 4 weeks. Pelleted feed was used for the first-stage weaners for the next 4 weeks while they grew to an average of 16 kg or 35 lbs. Medicated feed (see below) was used for the first ten days of this period. The growth to market weight (95 kg or 209 lbs) took another 16 weeks. The medicated feed used for the first ten days in first-stage weaners contained, in addition to 13,000 iu/kg Vitamin A, 2,000 iu/kg Vitamin D_3, 250 mg/kg Alpha Tocopherol, and 1.62% Lysine, the following additives:

- Cupric sulfate to give 160 mg/kg copper for growth promotion,
- 40 mg/kg Avilamycin to improve weight gain and feed conversion,
- 2,400 mg/kg zinc for the treatment and control of diarrhea, and
- 200 mg/kg Tilmicosin for the treatment of pneumonia.

This medicated feed (Startrite 88 + Maxus) carried the following directions for use:

- CONTAINS POM [Prescribe-Only-Medication] MEDICATION [sic.]. KEEP AWAY FROM CHILDREN. FOR ANIMAL FEED ONLY. USE IN ACCORDANCE WITH YOUR VETERINARY PRESCRIPTION.
- Do not feed with any other antibiotic feed additives.
- Feed for 15 days.

- Incompatible with feed containing ionophores.
- Do not feed to animals other than pigs, particularly sheep. Do not allow sheep access to effluent from treated pigs.
- Do not feed for a period exceeding 14 days.
- Do not feed to animals over 10 weeks.
- Withdraw 28 days prior to slaughter.

All medicines administered and dispensed were recorded in a "user record," a bound book kept on premises; the veterinarian stated that he kept another copy in his office. This "user record" was signed by the attending veterinarian during each visit and listed what medications were administered to and/or prescribed for to individual and animals and for groups of animals in certain developmental stages. The District Veterinary Office was responsible for reviewing these records; this was accomplished randomly for farms; the attending veterinarian's records were also reviewed, on the average, every three years. The reviewing Veterinary Inspector signed and dated the record book. In the event that these reviews might indicate a possible violation, a Special Investigation Unit would be called in.

♦ The condition of the "user record" was a cause for concern. The book on this farm was paper-covered and held together with a single staple; the staple was coming loose and several pages had come free. The pages were not numbered. The DAFRD officials ordered an improved and more secure record to be used, starting immediately.

A number of medications were kept in a locked closet; only the farmer and his manager had keys to the lock. Some of these medications were current; others had expired. The following current medications were present:

- Stresnil (azaperone)
- Amoxicillin
- Tiamulin (for dysentery)
- Oxytetracycline
- Streptomycin
- Dexamethasone
- Oxytocin

The following medications had expired but were stored together with the current medications:

- Benzylpenicillin (expired July 2001)
- A mix of procaine penicillin, streptomycin, neomycin, and prednisolone designated for intramammary use in cattle with mastitis—expired July 2001 (The farmer said he used it for preputial infections in his teaser boars.)
- Synthetic prostaglandin (expired May 2001)
- Vitamin E + Selenium (2½ 100cc-vials; all carried an expiration date of 10/31/99)
- Menbutone, a digestive stimulant, for sows after farrowing (expired February 1998)

The DAFRD officials expressed concern about the expired medications, and required them to be segregated and discarded.

The farmer stated that he did not use the expired medications, but they were not segregated in any way from unexpired medications. He also stated that no antibiotics were ever used on animals during the finishing stage, and that, if an animal in the finishing stage should become ill, it would not be treated but would be segregated. If it should not recover, it would be allowed to die or be euthanized, he said.

Cattle Feedlot

A visit was paid to a cattle feedlot that was in integral part of a large (1,500-acre) equine stud farm in near Kildare, County Kildare, on November 16. DAFRD was represented by Mr. Kilian Unger, Superintending Veterinary Officer. Approximately 200 cattle were in the feed lot at the time of the visit.

Meticulous documentation of all drug use was kept in a hardbound herd register with serially numbered pages. The attending veterinarian also kept his own record of drugs administered and dispensed. The only medication on hand for dispensation by the manager was ivermectin for endo- and ectoparasites. The District Veterinary Office was responsible for reviewing these records; this was accomplished randomly for farms; the attending veterinarian's records were also reviewed, on the average, every three years. The reviewing Veterinary Inspector signed and dated the record book. In the event that these reviews might indicate a possible violation, a Special Investigation Unit would be called in. Compliance with withdrawal times was the responsibility of the feedlot owner.

The feed consisted of either grass silage or whole-crop (wheat or barley) silage; the only additive used was a balancer consisting of minerals (brewer's yeast) and vitamins.

Each animal's "passport" (part of the Cattle Movement Monitoring System—see the section on Animal Disease Controls) accompanied the animal to slaughter.

All injured or sick animals must be accompanied by documentation from the attending veterinarian or they would not be accepted by the slaughter establishment or the ante-mortem DAFRD Veterinary Inspector. This documentation must be in the possession of the driver of the delivery vehicle, and must accompany the animals at all times.

Other drugs that may be dispensed to feed lot owners included medications that would require a course of treatment, e.g., antibiotics for pneumonia. All must be meticulously labeled with the following information:

- The name of the herd owner,
- The condition for which the treatment was initiated,
- The product name,
- The dosage,
- The period of treatment,

- The date issued, and
- The batch number of the medication.

All Prescription-Only Medicines (POMs) may only be administered or prescribed after examination of the herd by a licensed veterinarian.

SLAUGHTER/PROCESSING CONTROLS

The Irish inspection system had controls in place to ensure adequate humane handling and slaughter, ingredients identification, control of restricted ingredients, formulations, packaging materials, laboratory confirmation, label approvals, inspector monitoring, processing records, post-processing handling, processing defect actions by establishment personnel, and processing control by inspection personnel.

Additionally, establishments had adequate controls in place to prevent meat products intended for Irish domestic consumption from being commingled with products eligible for export to the U.S.

The following deficiencies were noted:

- Insanitary dressing procedures were identified in two of the three slaughter establishments. In Est. 356, obvious fecal material was found on a pork carcass and an approximately eight-inch length of spinal cord material in another. In Ests. 332 and 355, employees were observed to contaminate their hands by handling the anus in the bung-dropping process without washing their hands between carcasses. DAFRD ordered immediate corrective actions.

- Contaminated product was not adequately reconditioned in Est. 356. Several carcasses, that had apparently fallen onto the floor and were obviously contaminated with dirt and grease, had been hung back onto rails in a cooler together with clean carcasses, under crowded conditions, so that there was extensive contact between the dirty and the (previously) clean adjacent carcasses. One of the Superintending Veterinary Inspectors ordered a complete reinspection of all the carcasses in the cooler.

- Edible product was found to have been stored under insanitary conditions in Ests. 355 and 356. Corrective actions by the management personnel were prompt.

- Product was brought into the main production area in Est. 356 before it had passed pre-operational sanitation inspection. One of the Superintending Veterinary Inspectors commented on the fact to the Auditor shortly after entering the area, but no corrective action was taken until the other Superintending Veterinary Inspector, who was leading the audit, ordered re-cleaning of the entire area.

- Restricted ingredients (large sacks of pure nitrite) were not kept under adequate security in Est. 738. They were stored on a shelf in plain sight in the main ingredients room, that

was not secure. There was no running inventory of the material, and the amount on hand was not routinely reconciled with the amount received. The Superintending Veterinary Inspector ordered prompt implementation of a secure, inventoried nitrite storage policy.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs in Ests. 332, 355, and 738 were found to meet the basic FSIS regulatory requirements. In Est. 356, the audit was interrupted by the in-plant DAFRD Veterinarian-In-Charge when pre-operational sanitation was found to be inadequate during reinspection following orders for a complete re-cleaning of all product-contact surfaces when many pre-operational sanitation deficiencies had been identified, and the establishment was delisted by the DAFRD officials without proceeding with the remainder of the planned audit. The FSIS Auditor was in complete agreement with this decision. The establishment's HACCP documents were not audited in detail as a result; however, these documents had been audited, by the same FSIS Auditor, during the last audit of Ireland in April-May 2000, and had been found to be acceptable.

Testing for Generic *E. coli*

Ireland had adopted the FSIS regulatory requirements for *E. coli* testing. Three of the four establishments were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements, with the following exception:

- In the three slaughter establishments, baseline studies had not been conducted, as required for the swab-sampling procedure, to determine the "normal" levels of generic *E. coli*, nor had any of these establishments developed a statistical process control procedure for evaluating the results of the *E. coli* testing. The establishments were instead, evaluating the results using the method reserved for excision sampling. The Auditor explained the requirement in detail, and provided an example of how a baseline study could be conducted and how to develop a statistical process control; the responsible quality control individual agreed to initiate the program immediately.

.

ENFORCEMENT CONTROLS

Inspection System Controls

Except as noted below, the DAFRD inspection system controls [ante-and post-mortem inspection procedures and dispositions, control of restricted product and inspection samples, control and disposition of dead, dying, diseased or disabled animals, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls were in place and effective in ensuring that products produced by the establishments were wholesome, unadulterated, and properly labeled. These controls included the taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, the importation of only eligible livestock from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat products from other counties for further processing]. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

Three of the establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Ireland had adopted the FSIS regulatory requirements for *Salmonella* testing with exception of the following equivalent measures:

1. Program development: establishments certified to export meat to the United States develop their own *Salmonella* testing program and the program is approved by Ireland.

2. Sample collection: establishment personnel collect the samples, and Ireland provides oversight and monitoring of the establishment's sampling procedures,

3. Laboratories: Ireland uses a private laboratory for *Salmonella* testing, which:
   - has been accredited by Ireland,
   - has suitable facilities and equipment, properly trained personnel, reporting and record-keeping capabilities, and a written quality assurance program, and
   - reports test results directly to the government of Ireland.

The Auditor verified that Ireland had adopted the FSIS regulatory requirements for *Salmonella* testing as stated above, and that the *Salmonella* testing programs, as implemented in the establishments, were found to meet the basic FSIS regulatory requirements.

Ireland had adopted the FSIS performance standards for *Salmonella*. There had been no performance standard failures in swine or beef. If performance standards were exceeded, the

actions specified in the USDA rule would apply: at the first failure, measures would be taken to correct the problem, at the second, a review of the HACCP system would be undertaken and, at the third, inspection would be withdrawn. All levels of DAFRD would be involved in these actions.

Samples for *Salmonella* testing were delivered to the private lab the same day they were taken, and were either analyzed the same day they were received. Results were reported to both establishment and DAFRD officials independently. The owner or operator is legally required, under Irish law, to report to the Minister of Agriculture any result that can have negative public health effects. In 1999, an establishment (not USDA-certified) was suspended for failure to report such a result.

Species Verification

At the time of this audit, Ireland was exempt from the species verification requirement, having advised FSIS in writing that the following five conditions were being met:

1. Carcasses and products are transported between establishments in devices which are sealed with a tamper-detectable inspection seal by the Inspection Service at the originating establishment and broken by the Inspection Service at the receiving establishment.
2. Brands and sealing devices used by the Inspection Service to identify and seal product are kept under Inspection Service security.
3. Establishments are under continuous Inspection Service supervision while operating. No operations may take place without Inspection Service supervision.
4. Only one species of livestock or meat is allowed in the slaughter or processing areas at one time.
5. Product must be exported to the United States in a cargo container sealed by the Inspection Service.

During the audit, the auditor verified that these conditions continued to be met. With regard to the fifth condition, the seals applied by the inspection service were supplied by the establishment of origin, and not issued by the inspection service.

Monthly Reviews

FSIS requires monthly supervisory visits to U.S.-listed establishments during any month when they are producing U.S.-eligible product. These reviews were being performed by six Regional Veterinary Officers, who headed the six Public Health Regions. They performed the initial periodic reviews, and reported directly to Dr. Paddy Rogan. There was also a headquarters level of review, headed by Dr. Frank Kenny. All the internal reviewers were veterinarians with at least five years of experience in meat inspection, and had full authority up to and including delistment of the establishment. The schedule of the internal reviews was arranged by the Regional Veterinary Officers, each of whom developed the program in

his region and determined the establishment selection on the basis of compliance, performance, and the findings of headquarters reviews.

The internal review program was not applied equally to both export and non-export establishments; however, all abattoirs were subject to daily veterinary inspection by local authorities. Both regional and headquarters reviews were usually unannounced, but occasionally were announced (48 hours maximum advance notice for regional; 4-5 days for headquarters reviews), and were usually conducted by a team of at least two reviewers, at least once monthly. The records of audited establishments were kept by the individual auditors; some were also available in the inspection offices of the individual establishments, but not all. Copies were routinely maintained on file for at least three years.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, the inspection report is examined in detail, then a corrective action program is formulated and, and announced and unannounced visits are paid by regional and headquarters reviewers, whose reports must be favorable for the establishment to be considered for reinstatement.

After observing the internal reviewers' activities in the field, the auditor was confident in their professionalism, thoroughness, and knowledge of U.S. requirements, and in the effectiveness of Ireland's internal review program as a whole.

Enforcement Activities

Irish meat inspection authorities demonstrated a well-developed enforcement program. A deficiency noted by inspection personnel was recorded on a Noncompliance and Corrective Action Report. Further noncompliance triggered the generation of a Notice under Regulation 12 (6) – Fault Identification/Correction, usually called a "Twelve-Six," a legally binding document requiring the establishment to correct a deficiency within the time period specified by the inspection official in the document. In the event that this does not achieve the expected results, or in case of a noncompliance that indicates a public health risk, a Notice under Regulation 12. (7), or "Twelve-Seven" would be issued, which requires the "person in charge of the plant:

(a) to reduce the rate of throughput to a level consistent with acceptable hygiene standards, or
(b) to temporarily suspend the use of the equipment [identified], or
(c) to temporarily suspend the use of the [specified] plant areas for the preparation, handling, packaging, storage or loading of fresh meat, or
(d) to temporarily suspend the production activity [specified] pending the elimination of the identified defects.

The inspection official issuing this document would strike through the non-applicable measures. The auditor observed the issuance of all three of the above documents during the course of the audits of the establishments.

The Irish officials also provided summaries of several enforcement activities.

1. A summary of the prosecution and sentencing of three persons for (1) possession of meat not bearing a health mark, (2) supply of meat not bearing a health mark, and (3) application of a health mark to meat by a person not authorized to do so;

2. The chronology of an investigation for a positive *Listeria monocytogenes* finding in a routine sample of a cooked poultry meat product; and

3. A summary of an investigation of an instance of failure of the management of an establishment to notify the Minister of Agriculture, as required by Irish legislation, of any information pertaining to serious food safety risks associated with its products. In this case, the risk involved the finding of *Salmonella* species in a food product. The establishment's operations were suspended by DAFRD.

Exit Meeting

On the morning of November 27, an exit meeting was held in the Dublin offices of the Department of Agriculture, Food, and Rural Development (DAFRD), and was attended by Mr. Paddy Rogan, Deputy Chief Veterinary Officer; Mr. Frank Kenny, Senior Superintending Veterinary Inspector (Agriculture House); Mr. Kilian Unger and Mr. David Nolan, Superintending Veterinary Inspectors; Mr. Paul Rafter and Dr. Montserrat Gutierrez, Central Meat Control Laboratory; Ms. Dierdre Dordan, Veterinary Medicines Section; Ms. Mary Curley, Assistant Principal Officer, Food Safety Liaison Unit; Mr. Bernard Hegarty, Contract Manager, Food Safety Authority of Ireland; and Ms. Catherine Murray, Administrator, Pigmeat, Poultry, and Eggs Division. FSIS was represented by Mr. Michael Hanley, Agricultural Attaché, American Embassy Dublin, Mr. Steve McDermott, International Policy Staff Officer, and Dr. Judd Giezentanner and Dr. Gary D. Bolstad, International Audit Staff Officers. The topics of discussion included the following:

1. The three pieces of European Community legislation that provide the basis for the criteria that Member States must use to approve for export any meat establishment,

2. A copy of the delistment notice for the unacceptable establishment (356), and

3. The audit findings, with special emphasis on those deficiencies that were repeat findings from the previous FSIS audit in 2000 (see the CONCLUSION section, below). Mr. Paddy Rogan, Deputy Chief Veterinary Officer, gave assurances (1) that all the corrective actions taken during the on-site audits would be reinforced, (2) that the DAFRD staff would continue to take preventive measures to ensure that the deficiencies would be prevented from recurring, and (3) that all the deficiencies identified by both the FSIS Auditor and DAFRD officials during the audits would be carefully reviewed by himself and the other central authority officials and that they would ensure that they had been or would be promptly addressed and corrected.

CONCLUSION

The inspection system of Ireland was found on the whole, except as noted above, to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments.

The major concerns that arose as the result of this audit were the following:

- Insanitary storage of product was found in two of the four establishments.
- Hand-washing facilities were inadequate in one establishment. This was a repeat finding.
- None of the slaughter establishment management officials had developed a statistical process control, as required, to evaluate the results of the generic *E. coli* testing.
- Turnaround times in some sections of the three residue testing laboratories did not meet FSIS expectations. This was a repeat finding, although improvements were seen in some other sections of the laboratories compared with the 2000 FSIS audit.
- The intra-laboratory check sample programs in the residue testing laboratories did not meet FSIS requirements. This was a repeat finding.

Four establishments were audited: two were acceptable, one was evaluated as acceptable/re-review, and one was determined by the Irish supervising meat inspection officials to fail to meet FSIS requirements and was therefore found unacceptable, and the latter was removed by them from the list of establishments eligible to export meat products to the United States, effective as of the start of operations on the day of the audit. The deficiencies encountered during the on-site establishment audits, in those three establishments that were found to be acceptable, were adequately addressed to the auditor's satisfaction.

Dr. Gary D. Bolstad
International Audit Staff Officer

(signed) Dr. Gary D. Bolstad

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing
D. Data collection instrument for *Salmonella* testing
E. Laboratory Audit Forms
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. identified	7. Docu-mentation done daily	8. Dated and signed
332	√	√	√	√	√	√	√	√
355	√	√	√	√	√	√	√	√
356	*	*	*	*	*	*	*	*
738	√	√	√	√	√	√	√	√

356: The audit was interrupted by the in-plant DAFRD Veterinarian-In-Charge when pre-operational sanitation was found to be inadequate during reinspection following orders for a complete re-cleaning of all product-contact surfaces when many pre-operational sanitation deficiencies had been identified, and the establishment was delisted by the DAFRD officials without proceeding with the remainder of the planned audit. The FSIS Auditor was in complete agreement with this decision. The establishment's SSOP documents were not audited in detail as a result; however, these documents had been audited, by the same FSIS Auditor, during the last audit of Ireland in April-May 2000, and had been found to be acceptable.

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. All hazards identified	4. Use & users included	5. Plan for each hazard	6. CCPs for all hazards	7. Monitoring is specified	8. Corr. actions are described	9. Plan validated	10.Adequate verific. procedures	11.Adequate documentation	12. Dated and signed
332	√	√	√	√	√	√	√	√	√	√	√	√
355	√	√	√	√	√	√	√	√	√	√	√	√
356	*	*	*	*	*	*	*	*	*	*	*	*
738	√	√	√	√	√	√	√	√	√	√	√	√

356: The audit was interrupted by the in-plant DAFRD Veterinarian-In-Charge when pre-operational sanitation was found to be inadequate during reinspection following orders for a complete re-cleaning of all product-contact surfaces when many pre-operational sanitation deficiencies had been identified, and the establishment was delisted by the DAFRD officials without proceeding with the remainder of the planned audit. The FSIS Auditor was in complete agreement with this decision. The establishment's HACCP documents were not audited in detail as a result; however, these documents had been audited, by the same FSIS Auditor, during the last audit of Ireland in April-May 2000, and had been found to be acceptable.

Attachment C

Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
332	√	√	√	√	√	√	√	√	No	√
355	√	√	√	√	√	√	√	√	No	√
356	*	*	*	*	*	*	*	*	No	*
738	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

9 None of the Irish establishment management officials had understood the requirement that a statistical process control is to be developed to evaluate the results of the generic *E. coli* testing. All three were using the evaluation criteria reserved for the excision method. The Auditor carefully explained the requirement and provided an example of how a statistical process control may be developed.

356: The audit was interrupted by the in-plant DAFRD Veterinarian-In-Charge when pre-operational sanitation was found to be inadequate during reinspection following orders for a complete re-cleaning of all product-contact surfaces when many pre-operational sanitation deficiencies had been identified, and the establishment was delisted by the DAFRD officials without proceeding with the remainder of the planned audit. The FSIS Auditor was in complete agreement with this decision. The establishment's documents were not audited in detail as a result; however, these documents had been audited, by the same FSIS Auditor, during the last audit of Ireland in April-May 2000, and had been found to be acceptable.

Attachment D

Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.

2. Carcasses are being sampled.

3. Ground product is being sampled.

4. The samples are being taken randomly.

5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is/are being used for sampling.

6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
332	√	√	N/A	√	√	N/A
355	√	√	√	√	√	N/A
356	*	*	N/A	*	*	N/A
738	N/A	N/A	N/A	N/A	N/A	N/A

356: The audit was interrupted by the in-plant DAFRD Veterinarian-In-Charge when pre-operational sanitation was found to be inadequate during reinspection following orders for a complete re-cleaning of all product-contact surfaces when many pre-operational sanitation deficiencies had been identified, and the establishment was delisted by the DAFRD officials without proceeding with the remainder of the planned audit. The FSIS Auditor was in complete agreement with this decision. The establishment's documents were not audited in detail as a result; however, these documents had been audited, by the same FSIS Auditor, during the last audit of Ireland in April-May 2000, and had been found to be acceptable.